Procedure Manual

for the i-STAT® System

This Procedure Manual is intended to be a template for the Procedure Manual required by CLIA and laboratory accreditation bodies. This Procedure Manual should be customized for site-specific policies and procedures. The Procedure Manual is provided on disk for this purpose. This Procedure Manual is not intended to replace the System Manual.

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PROCEDURE MANUAL FOR THE i-STAT SYSTEM

Contents

System Overview **1**
- Analyzers
- Analysis Time
- Cartridges
- Glucose Test Strips
- Central Data Station or Data Manager

Supplies and Storage Requirements **1-2**
- Cartridges
- Glucose Test Strips
- Controls

Blood Specimens **2-5**
- Blood Collection Equipment
- Blood Volume
- Suitable Specimens
- Specimen Labeling
- Specimen Collection and Handling
- Criteria for Specimen Rejection
- Precautions

Procedure for Analysis **6-10**
- Preparation for Use
- Procedure for Cartridge Testing
- Procedure for Glucose Test Strip Testing
- Alternative Procedure

Results **11-18**
- Calculations
- Displayed Results
- Suppressed Results
- Printing and Transmitting Results
- Reference Ranges and Reportable Ranges
- Critical Results
- Interferences

Quality Control **19-23**
- Daily Procedures
- Monthly Procedures
- Periodic Procedures

Calibration **23**

Clinical Significance **24-26**

Principles of Measurement **27-28**

References **28**

Logs ..... **i-vii**

SYSTEM OVERVIEW

The i-STAT® System incorporates comprehensive components needed to perform blood analysis at the point of care. The System consists of the following primary components:

Analyzers

Analyzers can be the i-STAT Portable Clinical Analyzer, the i-STAT1 Analyzer, or the Blood Analysis Module, which is used in conjunction with the Philips Medical Systems (formerly Agilent Technologies) CMS and 24/26 Patient Monitor. When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring. A MediSense® Precision PCx™ or PCx™ Plus Glucose Test Strip is scanned and inserted into the i-STAT1 Analyzer and a drop of whole blood is applied to the target area of the test strip.

Analysis Time

- ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI cartridge: 600 seconds (10 min.)
- Other cartridges: typically 130 to 200 seconds
- MediSense Precision PCx or PCx Plus Glucose Test Strip: 20 seconds

Cartridges

A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, ***P***CO_2, ***P***O_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. Cartridges are also available for Celite-ACT, Kaolin-ACT, PT/INR, and Troponin I/cTnI (Table 1). A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Glucose Test Strips

The i-STAT1 Analyzer is capable of using the Abbott MediSense Precision PCx or PCx Plus Blood Glucose Test Strips.

Central Data Station or Data Manager

A dedicated desktop computer with the i-STAT Central Data Station program provides the primary information management capabilities for the i-STAT System. IR Links for Portable Clinical Analyzers, Downloaders and Downloader/Rechargers for the i-STAT1 Analyzers and a Philips installed server for Blood Analysis Modules allow for transmission of patient records from a widely distributed network of analyzers to the Central Data Station program. Data can be stored, organized, edited, and transferred to a laboratory information system or other computer system. Cartridge usage and efficiency reports can be generated for management of the system.

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

Cartridges are sealed in individual pouches or portion packs. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.** (Freezing will cause higher than expected ionized calcium results). Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

Glucose Test Strips

Test strips are sealed in individual foil packets. Store the strips at a temperature between 4 and 30°C (39 and 86°F). When stored properly, the unopened test strips remain stable until the expiration date printed on the barcode label. Do not freeze and keep out of direct sunlight.

Controls

i-STAT Controls for blood gases, electrolytes, and chemistries

Store at 2 to 8°C (35° to 46°F). Controls may be stored at room temperature (18 to 30°C or 64 to 86°F) for five days. Do not use after expiration date on the box and ampules.

i-STAT Controls for ACT and PT/INR

Store at 2 to 8°C (35° to 46°F). Do not use after expiration date on the box and vials. Controls should be used immediately after reconstitution.

i-STAT Controls for Cardiac Markers

Store at -18°C (-1°F) in a non-defrosting freezer. After thawing, the opened or unopened 1.0 mL vial is stable for 4 hours when capped and stored at 2 to 8°C (35° to 46°F). Do not refreeze

Hematronix Meter Trax™ Whole Blood Reference Controls for hematocrit

Store upright at 2 to 8°C (35° to 46°F). Do not allow to freeze. Ensure control is completely mixed before using. Once opened, bottles may be used for up to 31 days provided they have been resealed and refrigerated immediately after each use. Write the date of opening on the bottle label. Do not use after expiration date on box and vials.

Electronic Simulator

Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use.

MediSense Precision Glucose Control Solutions for test strips

Store the controls at temperatures between 4 and 30°C (39 and 86°F). Do not freeze. Each bottle of control solution is stable for 90 days after opening. Write the date of opening on the bottle label. Always make sure the cap is returned to the correct bottle and tightly closed immediately after use.

BLOOD SPECIMENS

Blood Collection Equipment

Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

- Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for electrolytes and blood gases)
- Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g., 1cc syringe and a 16 to 20 gauge needle).
- Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood)

Cartridges for ACT

- Skin puncture: not recommended
- Venipuncture and arterial puncture: plain plastic syringe without anticoagulant

Glucose Test Strips

- Skin puncture: lancet and capillary collection tube with lithium heparin, sodium heparin, or EDTA or direct application of sample to test strip
- Venipuncture and arterial puncture: collection tube or syringe with lithium heparin, sodium heparin, or EDTA

Cartridges for PT/INR

- ❑ Skin puncture: lancet only needed. Cartridge can be filled directly from the finger.
- ❑ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant.

Cartridges for Troponin I/.cTnI

- ❑ Skin puncture: not recommended.
- ❑ Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g. 1 cc syringe and a 16 to 20 gauge needle). Alternately, a plain syringe or plain collection tube and disposable transfer device can be used if the sample is tested within one minute of patient draw.

Blood Volume

See Table 1 below for cartridge volumes. For the glucose test strip, sufficient sample to cover target area - approximately one drop, is required.

Table 1: Cartridge Panel Configurations and Blood Volume

Cartridge	Vol. µL	pH	PCO_2	PO2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	ACT	PT/INR	cTnI	HCO3	TCO2	SO2	BE	Anion Gap	Hb
CG8+	95	•	•	•	•	•		•	•				•				•	•	•	•		•
EG7+	95	•	•	•	•	•		•					•				•	•	•	•		•
EG6+	95	•	•	•	•	•							•				•	•	•	•		•
CG4+	95	•	•	•								•					•	•	•	•		
G3+	95	•	•	•													•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•				•	•		•	•	•
6+	65				•	•	•		•	•			•									•
EC4+	65				•	•			•				•									•
E3+	65				•	•							•									•
G	65								•													
Crea	65										•											
ACT	40													•								
PT/INR	20														•							
cTnI	16															•						

Shading denotes calculated values

Suitable Specimens for Cartridges for Blood Gases, Electrolytes, Chemistries, and Hematocrit

- ❑ Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin.
- ❑ Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity.
- ❑ Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

Suitable Specimens for ACT

- ❑ Fresh whole blood without anticoagulant collected in a plastic syringe. If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or three to six dead space volumes of the catheter.
- ❑ Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge must be plastic.

Suitable Specimens for PT/INR

- ❑ Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- ❑ Fresh capillary whole blood dispensed directly into the cartridge from the finger.

Suitable Specimens for Glucose Test Strip

- Fresh capillary whole blood collected in a capillary collection tube containing sodium heparin, lithium heparin, or EDTA. Test immediately.
- Fresh venous whole blood collected in a collection tube containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.
- Fresh arterial whole blood collected in a syringe containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.

Suitable Specimens for Troponin I/cTnI

- Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Collection tubes must be filled at least half full.
- Non heparinized whole blood samples tested within one minute of patient draw collected into a plastic syringe or plastic evacuated tube containing no additives.

Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information:

Patient name, sex, age
Patient ID number
Time and date of collection
Phlebotomist ID
Doctor's name

Specimen Collection and Handling

In-Dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter, connectors, and needle. If collecting sample for ACT, clear the line first with 5mL saline and discard the first 5mL of blood.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used. Do not expose sample to air or $\boldsymbol{P}CO_2$ may decrease, pH may increase and $\boldsymbol{P}O_2$ may decrease if the value is above or increase if the value is below the $\boldsymbol{P}O_2$ of room air (approximately 150 mmHg).

For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.

For glucose test strips, fill to capacity a syringe or collection tube containing lithium heparin, sodium heparin, or EDTA.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test sample collected without anticoagulant immediately. Test samples for ACT and PT/INR immediately. Test samples for lactate within 3 minutes of sample collection. For pH, blood gases and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. For the glucose test strip and other cartridge tests, test sample within 30 minutes of collection.

Venous Specimens

For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing sodium, lithium, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of sodium or lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may

affect other results. The use of partial – draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended because of the potential for decreased measured PCO2 results and calculated HCO_3 and TCO_2 values.

For cartridge testing of ACT or PT/INR, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

For glucose strip testing, EDTA is also an acceptable anticoagulant.

Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test Sample collected without anticoagulant immediately. Test samples for ACT and PT/INR immediately. Test samples for lactate within 3 minutes of sample draw. Test samples for pH, PCO2, and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For the glucose test strip and other cartridge tests, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

For tests other than PT/INR, wipe away the first drop of blood, which contains excess tissue fluid which can increase the potassium result and decrease other test results. Avoid drawing air into the capillary tube. Use balanced heparin or plain capillary tubes for ionized calcium. Test samples immediately to avoid clotting (especially in neonates). Capillary samples are not recommended for ACT or Troponin I/cTnI.

Criteria For Specimen Rejection

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin
- Specimens for ACT or PT/INR collected in glass syringe or tube or with anticoagulant of any kind
- Syringe for pH, $\boldsymbol{P}CO_2$, and $\boldsymbol{P}O_2$ with air bubbles in sample
- Incompletely filled vacuum tube for the measurement of ionized calcium or $\boldsymbol{P}CO_2$
- Other sample types such as urine, CSF, and pleural fluid

Precautions: Avoid the Following Circumstances

- Drawing a specimen from an arm with an I.V.
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site, or a traumatic draw)
- Icing before filling cartridge
- Time delays before filling cartridge, especially lactate, ACT, and PT/INR
- Exposing the sample to air when measuring pH, $\boldsymbol{P}CO_2$, and $\boldsymbol{P}O_2$

PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Glucose test strips require no preparation for use.

Procedure for Cartridge Testing (other than PT/INR or Tropnin I/cTnI)

1. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well.
3. Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
4. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
5. Insert the cartridge into the cartridge port on the analyzer until it clicks into place. When using an ACT cartridge, the analyzer must remain horizontal during the testing cycle.
6. Never attempt to remove a cartridge while the LCK or "Cartridge Locked" message is displayed.
7. Enter an operator ID number. Repeat if required.
8. Enter the patient ID number. Repeat if required.
9. Select tests to be reported, if prompted.
10. Enter additional parameters on the Chart Page if required:
    - Patient temperature can be entered as degrees Centigrade or Fahrenheit. (Use the * key on the i-STAT Portable Analyzer for a decimal point.)
    - FIO_2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - Fields 1, 2, and 3 are user-defined fields, typically used for ventilator settings such as PIP or PEEP.
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field. Select CPB for patient in cardiopulmonary bypass surgery.
11. View results shown on the analyzer's display screen.

Procedure for the i-STAT1 Analyzer with Information First

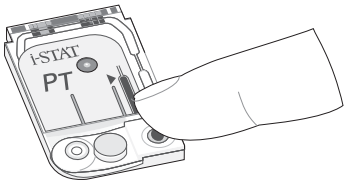
1. Turn the analyzer on and press 2 for i-STAT Cartridge.
2. Scan or enter the operator and patient IDs. Repeat if prompted.
3. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
4. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
5. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
6. Insert the cartridge into the cartridge port until it clicks into place. When using an ACT cartridge, the analyzer must remain horizontal during the testing cycle.
7. Select tests to be reported, if prompted.
8. Enter additional parameters on the Chart page if required:
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
    - Fields 1, 2, and 3 are user-defined fields, typically used for ventilator settings such as PIP or PEEP.
    - Patient temperature can be entered as degrees Centigrade or Fahrenheit.
    - FIO_2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - Choose 1-YES or 2-NO for CPB.
    - Press the $\rightarrow$ key to return to the results page.

9. View results shown on the analyzer's display screen.
10. Enter Comment Code if prompted.

Procedure for PT/INR Cartridge Testing

Skin Punctures

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device.
5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. Avoid strong repetitive pressure, ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.
10. Insert the cartridge into the cartridge port until it snaps into place.
11. Enter an operator ID number. Repeat if required.
12. Enter the patient ID number. Repeat if required.
13. Select tests to be reported, if prompted.
14. Enter additional parameters on the Chart Page, if required.
15. View result on the analyzer's display screen.



Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat vibration-free surface for testing.

Procedure for Troponin I/cTnI Testing

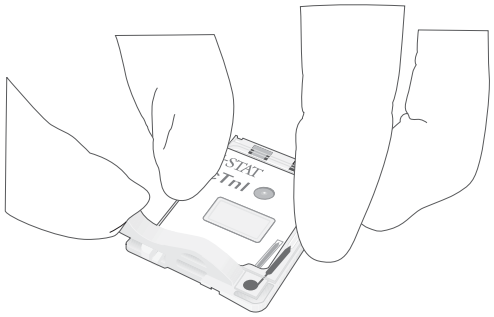
Note: The i-STAT cTnI cartridges can only be used with the i-STAT 1 Analyzer bearing the i immuno symbol.

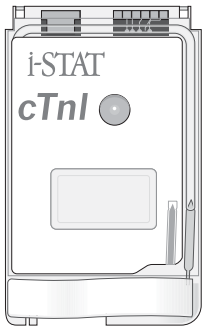
This symbol is located on the grey casing next to the lower right corner of the analyzer display screen. Before testing cTnI cartridges on the i-STAT 1 Analyzer, the analyzer must be customized through the Central Data Station (CDS) or through the analyzer's Customization menu for the following options:

1. Cartridge Barcode Required, or
2. Cartridge Information First Required AND Cartridge Lot Number Required.

Cartridge Test Procedure (Non-Information First Customization)

1. Remove cartridge from portion pack. Do not immediately dispose of the portion pack, as the cartridge lot number listed on it will be scanned into the analyzer during the testing procedure. Handle the cartridge from its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
2. Following thorough mixing of the sample, direct the transfer device (either syringe tip or pipette tip) into the inlet port. Apply a single drop of sample to the inlet port. If the cartridge fill is incomplete as seen via the fill indicator on the cartridge label, apply a second small drop until the sample reaches the fill mark.
3. To close the cTnI cartridge:
    a. first anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cTnI cartridge from its side edges away from the sample inlet.
    b. use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. Note: When sliding the closure clip, the index finger of that same hand should not be placed directly across from the thumb, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not used at all.

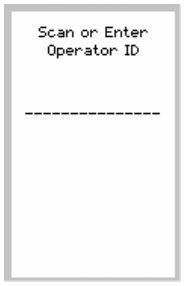




4. Insert the cartridge into the cartridge port. Do not attempt to remove the cartridge while the Cartridge Locked message is displayed.
5. Scan the Cartridge Lot number from the cartridge portion pack (Screen 1 below).
6. Scan or Enter Operator ID (Screen 2 below). Repeat if prompted.
7. Scan or Enter Patient ID (Screen 3 below). Repeat if prompted.

    The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
8. Select tests to be reported, if prompted.
9. Enter sample type on chart page if applicable.
10. The Time to Results countdown bar will then be displayed (Screen 4 below). Once time has elapsed, view results on analyzer's display (Screen 5 below).
11. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

Screen 1



Screen 2

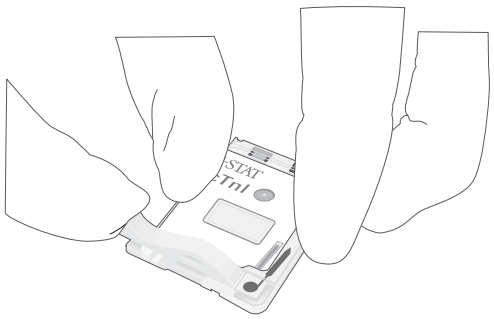
Screen 3

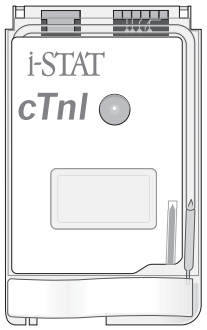
Screen 4

Screen 5

Cartridge Test Procedure (Information First Customization)

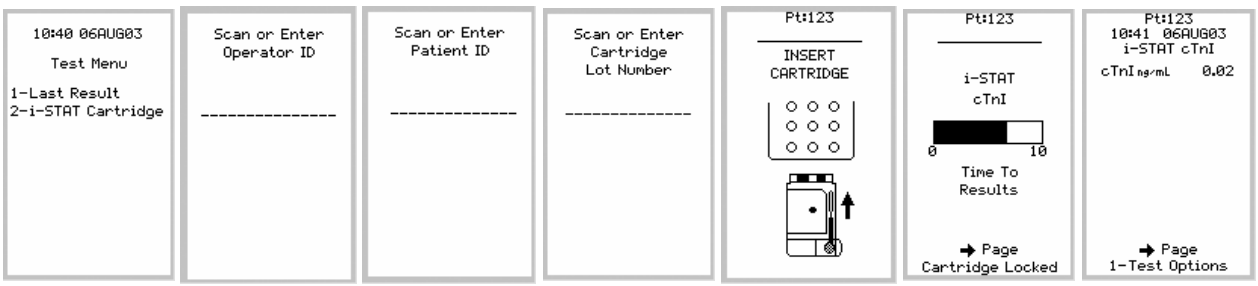
1. Press the On/Off key to turn analyzer on.
2. Press 2 for i-STAT Cartridge from the Test Menu (Screen 1 below).
3. Scan or Enter Operator ID (Screen 2 below). Repeat if prompted.
4. Scan or Enter Patient ID (Screen 3 below). Repeat if prompted.
5. Scan Cartridge Lot number from the cartridge portion pack (Screen 4 below).
6. Remove cartridge from portion pack. Handle the cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
7. Following thorough mixing of the sample, direct the transfer device (either syringe tip or pipette tip) into the inlet port. Apply a single drop of sample to the inlet port. If the cartridge fill is incomplete as seen via the fill indicator on the cartridge label, apply a second small drop until the sample reaches the fill mark.
8. To close the cTnI cartridge:
    a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cTnI cartridge from its side edges away from the sample inlet.
    b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. Note: When sliding the closure clip, the index finger of that same hand should not be placed directly across from the thumb, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not at all.





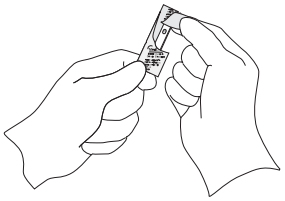
9. Insert cartridge into cartridge port (Screen 5 below). Do not attempt to remove the cartridge while the Cartridge Locked message is displayed.

    The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
10. Select tests to be reported, if prompted.
11. Enter sample type on chart page, if applicable.
12. The Time to Results countdown bar will then be displayed (Screen 6 below). Once time has elapsed, view results on analyzer's display (Screen 7 below).
13. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

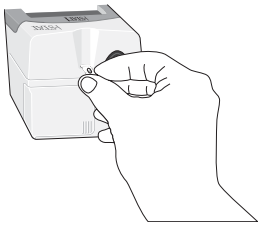


Screen 1 Screen 2 Screen 3 Screen 4 Screen 5 Screen 6 Screen 7

PCx Glucose Test Strip Procedure



1. Press the ⏻ (On/Off) key to turn the analyzer on.
2. Press 3 for PCx Glucose Strip.
3. Press 1 for Patient.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter patient ID. Repeat if prompted.
6. Scan or enter test strip lot number.
7. Press 1 for Arterial/Capillary or 2 for venous sample if prompted.



8. Open foil packet, remove test strip and insert into analyzer test strip port with black contact bars facing up and forward.
9. Apply drop of blood to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
10. Enter chart page information if applicable.
11. View results on analyzer's display.
12. Enter Comment Code if applicable.
13. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.

Alternative Procedure

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

RESULTS

Calculations

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results

There are three conditions under which the i-STAT System will not display results:

1. Results outside the System's reportable ranges are flagged with a < or > , indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependant on the result of a test flagged as either > or <.

   Action:
   Send specimen(s) to the laboratory for analysis.
2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *******.

   Action:
   Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.
3. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

   Action:
   Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual's Troubleshooting section or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Printing and Transmitting Results

Printing Results from the i-STAT Portable Clinical Analyzer to the HP Portable Printer (Note: The Martel Printer cannot be used with the i-STAT Portable Clinical Analyzer.)

1. Place the analyzer in the cradle of an IR Link or align the IR windows of the analyzer and printer. Turn the printer on (printer light red) or press the paper advance switch to reactivate.
2. To print the displayed test record, press the PRT key on the analyzer.
3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key.
4. Do not move the analyzer while "Printing" is displayed.

   Optional: Write the patient's name on the "Pt Name" line and the physician's name on the "Physician" line.

   Note: Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.

Printing Results from the i-STAT1 Analyzer to the Martel Portable Printer (Note: The HP printer cannot be used with the i-STAT 1 Analyzer.)

Without Downloader or Downloader/Recharger

1. Turn printer on if green power light is not on.
2. Align IR windows of analyzer and printer.
3. Display results.
4. Press the Print key.
5. Do not move analyzer or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

With Downloader or Downloader/Recharger

1. Place analyzer in Downloader or Downloader/Rechrager that is wired to the printer.
2. Display results.
3. Press the Print key.
4. Do not move analyzer or printer until printing is complete.

Printing more than one result

1. Turn the analyzer on.
2. Press the Menu key.
3. Press 2 for Data Review.
4. Press 7 for List.
5. Scroll through the test records using the ← and →keys.
6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
7. Align analyzer and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press the Print key.

Transmitting Results from the i-STAT Portable Clinical Analyzer to the Central Data Station

1. Place the analyzer in the cradle of an IR Link. The IR status light must be green.
2. With a test record on the display screen, press the * key.
3. Do not move the analyzer while "Transmitting" is displayed. During transmission the IR Link's light will blink alternately red and green. If transmission is successful, the IR Link will emit a single high-pitched beep and the light will return to green. An unsuccessful transmission is indicated by three low tone beeps. In this case repeat the transmission process. If unsuccessful the second time, notify the i-STAT System Coordinator.

Transmitting Results from the i-STAT1 Analyzer to the Data Manager

1. Place analyzer in a Downloader or Downloader/Recharger.
2. Do not move analyzer while the message "Communication in Progress" is displayed.

Reference Ranges[1,2], Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT System.

Cartridges

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
Sodium	mmol/L	138 – 146	138 - 146	100 – 180	mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L
Potassium	mmol/L	3.5 – 4.9	3.5 - 4.9	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L	98 – 109	98 – 109	65 – 140	mmol/L x 1 = mEq/L
BUN	mg/dL	8 – 26	8 – 26	3 – 140	mg/dL BUN x 0.357 = mmol urea/L Example: 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.0556 = mmol/L Example:
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	100 mg/dL = 5.55 mmol/L
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	g/L x 5.556 = mmol/L
Creatinine	mg/dL	0.6 - 1.3	0.6 - 1.3	0.2 - 20.0	mg/dL x 88.4 = mol/L
	μmol/L	53 - 115	53 - 115	18 - 1768	
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	Example: 1.13 mmol/L x 4 = 4.52 mg/dL
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.00	N/A
***P*CO$_2$**	mm/Hg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa Example: 35 mmHg x 0.133 = 4.66 kPa
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	
pO$_2$	mm/Hg	80 – 105		5 – 800	mmHg x 0.133 = kPa Example: 83 mmHg x 0.133 = 11.04 kPa
	kPa	10.7 – 14.0		0.7 – 106.6	

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
Hematocrit	%PCV Fraction	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51	10 – 75 0.10 – 0.75	% PCV x 0.01 = Volume fraction Example: 40% PCV = 0.40 PCV
Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90-1.70 8.1–15.3	0.30 – 20.0 2.7 – 180.2	mmol/L x 9.01 = mg/dL
HCO_3*	mmol/L	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO_2*	mmol/L	23 – 27	24 - 29	1 – 85	
BE_{ecf}*	mmol/L	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)	
Anion Gap*	mmol/L	10 – 20	10 – 20	(-10) – (+99)	
sO_2*	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL g/L mmol/L	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11	3.4 – 25.5 34 – 255 2.1 – 15.8	g/dL x 10 = g/L
Celite ACT	seconds	74 – 125 (PREWRM) 84 – 139 (NONWRM)	74 – 125 (PREWRM) 84 – 139 (NONWRM)	50 - 1000	
Kaolin ACT	seconds	74 – 137 (PREWRM) 82 – 152 (NONWRM)	74 – 137 (PREWRM) 82 – 152 (NONWRM)	50 - 1000	
Troponin I/cTnI	ng/mL (µg/L)		0.00 – 0.03**	0.00 –50.00##	
Prothrombin Time/PT	INR			0.9-8.0#	

*Calculated values.
#Performance characteristics have not been established for INRs above 6.0.
**Represents the 0 – 97.5% range of results. Each facility should establish it's own reference range using the i-STAT cTnI assay.
##Performance characteristics have not been established for cTnI values above 35.00 ng/mL.

Glucose Test Strip

UNIT	REFERENCE RANGE	REPORTABLE RANGE	UNIT OF CONVERSION
mg/dL	Fasting: 70 – 105 Two hours after meal: less than 140	20 – 600	mg/dL x 0.0556 = mmol/L
mmol/L	Fasting: 3.9 – 5.8 Two hours after meal: less than 7.8	1.1 – 33.3	

Critical Results[3]

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse.

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	**high**	**low**	**high**	**low**	**high**
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
$\boldsymbol{P}CO_2$ (mmHg)	19	67	21	66	–	–
$\boldsymbol{P}O_2$ (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Lactate						
Hematocrit (%PCV)	18	61	20	62	33	71
Celite ACT						
PT/INR						
Kaolin ACT						
Troponin I/cTnI						

Interferences

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured. For example, in the table below, β-hydroxybutyrate at sample concentration level of 16 mmol/L would decrease the measured sodium by 5 mmol/L.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	β-hydroxybutyrate	16 mmol/L (166 mg/dL)	Decrease (↓) Na by 5 mmol/L
	Lactate	20 mmol/L	Decrease (↓) Na by 5 mmol/L
	Bromide	37.5 mmol/L	Increase (↑) Na by 5 mmol/L
Chloride	β-hydroxybutyrate	16 mmol/L (166 mg/dL)	Increase (↑) Cl by 3 mmol/L
	Bromide	12.5 mmol/L (100 mg/dL)	Increase (↑) Cl by 30 mmol/L
	Lactate	11 mmol/L (100 mg/dL)	Increase (↑) Cl by 3.5 mmol/L
	Salicylate	4 mmol/L	Increase (↑) Cl by 5 mmol/L
	Thiocyanate	24 mmol/L (140 mg/dL)	May cause results to be suppressed (***)
Ionized Calcium	Magnesium	1.0 mmol/L above normal	Increase (↑) iCa by 0.04 mmol/L
	β-hydroxybutyrate	20 mmol/L	Decrease (↓) iCa by 0.1 mmol/L
	Lactate	20 mmol/L	Decrease (↓) iCa by 0.05 mmol/L
	Salicylate	4.34 mmol/L	Decrease (↓) iCa by 0.1 mmol/L
Glucose	Bromide	37.5 mmol/L (300 mg/dL)	Decrease (↓) glucose by 30 mg/dL
(Cartridge)	pH	pH: per 0.1 pH units below 7.4 @ 37°C	Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37°C	Increase (↑) glucose by 0.8 mg/dL (0.04 mmol/L)
	Oxygen	PO_2 less than 20 mmHg @ 37°C	May decrease (↓) glucose
	Hydroxyurea	100 μmol/L	Increase (↑) glucose 8 mg/dL (0.44 mmol/L)
	Thiocyanate	24 mmol/L (140 mg/dL)	Decrease (↓) glucose by approx. 23%
Glucose	Hematocrit	<20%PCV	Increase (↑) glucose
(Precision PCx Test Strip)		>70%	Decrease (↓) glucose
	Acetominophen	>100 μg/mL	Decrease (↓) glucose
Glucose **(Precision PCx Plus Test Strip)**	See package insert for full details.		
BUN/Urea	Thiocyanate	24 mmol/L (140 mg/dL)	Decrease (↓) urea by approx. 21%
Lactate (continued on next page)	Bromide	25 mmol/L (200 mg/dL)	Decrease (↓) lactate by 40%
	Cysteine	6.4 mmol/L (101 mg/dL)	Decrease (↓) lactate by 11%
	Hydroxyurea	100 μmol/L	Increase (↑) lactate 1.44 mg/dL (0.16 mmol/L)

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
	Glycolic Acid	10 mmol/L	Increase (↑) lactate by approx. 1.96 mmol/L from an initial Lactate concentration of 1.45 mmol/L
Creatinine	Acetaminophen	For every 1 mmol/L acetaminophen	Increase (↑) creatinine by 0.25 mg/dL
	Ascorbate	0.227 mmol/L	Increase (↑) creatinine by 0.7 mg/dL
	Bromide	12.5 mmol/L (100 mg/dL)	Increase (↑) creatinine by 0.8 mg/dL (71 μmol/L) from an initial Creatinine concentration of 1.0 mg/dL (88 μmol/L)
<2 mg/dL	***P***CO_2	Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg PCO_2
>2 mg/dL	***P***CO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg ***P***CO_2
	Hydroxyurea	100 µmol/L	Increase (↑) 1.85 mg/dL (164 µmol/L)
	Creatine	5 mg/dL creatine	Increase (↑) creatinine by 0.20 mg/dL
	N-acetylcysteine	16.6 mmol/L	Increase (↑) creatinine by 0.4 mg/dL
Hematocrit	White Blood Count (WBC)	Greater than 50,000 WBC/µL	May Increase (↑) hematocrit
	Total Protein	<u>For measured Hct<40%</u> For each g/dL below 6.5 For each g/dL above 8.0	Decrease (↓) Hct by 1% PCV Increase (↑) Hct by 1% PCV
		<u>For measured Hct≥40%</u> For each g/dL below 6.5 For each g/dL above 8.0	Decrease (↓) Hct by 0.75% PCV Increase (↑) Hct by 0.75% PCV
	Lipids	Abnormally high	Increase (↑) Hct
Celite ACT	Aprotinin		Falsely extends Celite ACT times
PCO_2	Propofol (Diprovan®)		For patients administered propofol or thiopental sodium, i-STAT recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
	Thiopental Sodium		

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QUALITY CONTROL

Daily Procedures

Analyzer Verification

Verify the performance of each handheld analyzer or Blood Analysis Module in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, PT/INR, and cTnI.

Action:

If PASS is displayed on the analyzer screen (after using the external Electronic Simulator):

- ❑ Remove the Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result to the Central Data Station.
- ❑ Use the analyzer as required.

Note: If the internal Electronic Simulator is used, the "PASS" message will not be displayed on the analyzer screen. The "PASS" record will appear in the analyzer's stored results for transmission to the Central Data Station.

Remedial Action:

If FAIL is displayed on the analyzer screen:

- ❑ Repeat the procedure with the same Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used. If PASS is displayed use the analyzer as required.
- ❑ If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

If PASS is displayed with the second Electronic Simulator:

- ❑ Use the analyzer as required.
- ❑ Deliver the questionable Electronic Simulator to the i-STAT System Coordinator.

If FAIL is displayed with the second Electronic Simulator:

- ❑ DO NOT analyze patient samples with the analyzer.
- ❑ Transmit the results to the Central Data Station.
- ❑ Deliver the faulty analyzer to the i-STAT System Coordinator.
- ❑ Record the failure in the i-STAT QC Log along with the action taken.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

- ❑ Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any expired cartridges to the i-STAT System Coordinator.
- ❑ Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- ❑ Document in the i-STAT QC Log.

Action:

If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C (35 to 46°F) use cartridges as required.

Remedial Action:

If the temperature is outside the range of 2 to 8°C (35 to 46°F), quarantine the cartridges in the storage refrigerator. Notify the i-STAT System Coordinator immediately. DO NOT USE the cartridges from this refrigerator. Record the QC failure in the i-STAT QC Log along with the action taken.

Room Temperature Cartridges

- ❑ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two weeks. Deliver any expired cartridges to the i-STAT System Coordinator.
- ❑ Verify that room temperature has not exceeded 30 °C.
- ❑ Document in the i-STAT QC log.

Action:

If the measured temperature of the room has been continuously below 30°C (86°F) use cartridges as required.

Remedial Action:

If the measured room temperature has exceeded 30°C (86°F) for any period of time:

- ❑ Quarantine the cartridges.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ DO NOT USE the cartridges.
- ❑ Record the out-of-control event in the i-STAT QC Log and the action taken.

Verification of Glucose Test Strip

Two levels, usually the Low and High Controls, are tested daily.

1. Press the ⏻ (On/Off) key to turn the analyzer on.
2. Press 3 for PCx Glucose Strip.
3. Press 1 for Patient.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter patient ID. Repeat if prompted.
6. Scan or enter test strip lot number.
7. Press 1 for Arterial/Capillary or 2 for Venous sample if prompted.
8. Open foil packet, remove test strip and insert into analyzer test strip port with black contact bars facing up and forward.
9. Apply drop of blood to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
10. Enter chart page information if applicable.
11. View results on analyzer's display.
12. Enter Comment Code if applicable.
13. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.

Action:

If the results are PASS, use the test strips as needed.

Remedial Action:

If the result is outside the acceptable range:

- ❑ Check that the correct lot numbers for control and test strip were scanned.
- ❑ Check storage conditions and that bottle has not been opened for more than 90 days.
- ❑ Use a new test strip. If results are in range, continue to use the test strips. If not, do not use the strips from this lot and notify the i-STAT System Coordinator.

Monthly Procedures

Print Electronic Simulator Results

Print a copy of the Electronic Simulator results from the Central Data Station. Include the report in the i-STAT QC Log.

- CDS version lower than 5: Click on System and Electronic Simulator.
- CDS version 5 and above: Click on the Simulator Viewer.

Print Control Fluid Analysis Results

Print results for any control fluids analyzed from the Central Data Station. Include the report in the i-STAT QC Log.

- CDS version lower than 5: Use the Trend function.
- CDS version 5 and above: Click on the Control Results Viewer.

Periodic Procedures for Cartridges

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Action:

- Fill out the record of receipt and forward materials to refrigerator.
- If all windows are white or if only the A windows is blue or the 1 window is red, then transit temperatures were satisfactory and the cartridges can be used.

Remedial Action:

If the B window is blue or the 2 window is red, contact the i-STAT System Coordinator before using cartridges. If the C or D windows are blue, or the 3 or 4 windows are red:

- Quarantine the suspect cartons.
- Notify the i-STAT System Coordinator immediately.
- DO NOT USE cartridges from the suspect cartons.
- Record the out-of-control event in the i-STAT QC Log.

Integrity Testing

From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT Level 1 and 3 Controls. If hematocrit is included, analyze Meter Trax Low and High Controls. For ACT cartridges, analyze i-STAT Level 1 and Level 2 ACT Controls. For PT/INR cartridges, analyze i-STAT Level 1 and Level 2 PT Controls. For cTnI cartridges, analyze i-STAT Level 1 and Level 3 Cardiac Marker Controls. Use any verified analyzer for control testing. Transmit the results to the Central Data Station. Use the expected values published in the package inserts to verify the integrity of the cartridges.

Procedure for testing cartridges with i-STAT Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure PO2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+ or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, PCO_2, or PO_2 (G3+, EG6+, EG7+, CG8+, or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.
2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the

solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.

3. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results.
   - ❑ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.
   - ❑ When using a syringe (1cc or 3cc syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
   - ❑ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
4. Compare results to the package insert values. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to the Central Data Station.

Procedure for testing cartridges with Hematronix Meter Trax Controls for hematocrit

1. Warm Meter Trax to room temperature, 18 - 30°C (64 -86°F).
2. Roll the vials upright in the palms several times, then invert the vials and repeat rolling in the palms several times. Continue inverting and mixing the vials for 2-3 minutes. Verify the uniform mixing of the vials by checking for clumping on the sides and bottom of the vials. If clumping is present, continue to roll the vials until all clumps are gone. If clumping remains after 5 minutes, discard the vial.
3. Fill and seal a cartridge and insert immediately into the analyzer. Note: The Control option from the Quality Tests menu must be used on the i-STAT1 Analyzer for Meter Trax controls.
4. After completion of testing, wipe the rim of the cap of the vial with a lint-free wipe, recap and return to the refrigerator.
5. Compare results to the package insert values. If results are within the expected ranges, use the cartridges as needed. Transmit results to the Central Data Station.

Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cartridges with i-STAT Level 1 and Level 2 ACT or PT/INR Controls

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
3. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
4. Use a plastic pipette, syringe, or capillary tube without anticoagulant to transfer the solution to an ACT cartridge.

5. Immediately seal the cartridge and insert it into an analyzer. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Compare results to the package insert values. If results are within the expected ranges, use the cartridges as needed. Transmit results to the Central Data Station.

Remedial Action:
If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cTnI cartridges, analyze i-STAT Level 1, 2, or 3 Cardiac Marker Controls:

1. Remove vial from freezer and thaw at room temperature (18-30ºC) for 15 minutes.
2. Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
3. Dispense a drop of sample directly from the vial into the i-STAT cTnI cartridge and seal the cartridge. If short-term storage (<4 hrs) is desired, tightly recap the bottle immediately, and store at 2-8ºC.
4. Insert cartridge into an i-STAT 1 Analyzer.

Target Values and Ranges: See value assignment sheet accompanying the control or calibration verification material. The value assignment sheet displays target values and ranges expected when materials and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods (i.e., other IVD instrumentation).

Always remember to analyze the control material in the Control pathway and the calibration verification material in the Cal Ver pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu.

Remedial Action:
If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT System Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Periodic Procedures for Glucose Test Strips

- ❑ Two levels, usually the Low and High Controls, are tested:
- ❑ When a new lot of test strips is opened.
- ❑ When diabetes medication plan is adjusted.
- ❑ When the strips have been exposed to temperatures outside the storage conditions (4-30°C, 39-86 °F).

CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.

For glucose test strips, lot-specific calibration information is encoded in the test strip barcode label.

CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyperinsulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Overhydration Thiazide therapy
Ionized Calcium	Dehydration Hyperparathyroidism Malignancies Immobilization Thiazide diuretics Vitamin D intoxication	Hypoparathyroidism Early neonatal hypocalcemia Chronic renal disease Pancreatitis Massive blood transfusions Severe malnutrition
BUN	Impaired renal function Prerenal azotemia (e.g. shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Overhydration Malnutrition
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g. Cushing's syndrome) Drugs (e.g. steroids, thyrotoxicosis) Chronic renal failure Stress IV glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/Massive liver disease Ethanol ingestion/Reactive hypoglycemia Glycogen storage disease

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolumia, left ventricular failure); diabetes mellitus, neoplasia, liver disease; drug or toxins (ethanol, methanol, salicylates); glycolic acid as a product of ethylene glycol metabolism	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis
***P*CO_2**	Acute Respiratory Acidosis: • *Depression of respiratory center* • *Suppressed neuromuscular system* • *Pulmonary disorders* • *Inadequate mechanical ventilation* Chronic respiratory acidosis • *Decreased alveolar ventilation* • *Hypoventilation* Compensation in metabolic alkalosis	Respiratory alkalosis: • *Increased stimulation of respirator center* • *Hypermetabolic states* • *Mechanical hyperventilation* Compensation in metabolic acidosis
***P*O_2**	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO_3	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis
Hematocrit	Dehydration Burns Impaired ventilation Renal disorders	Hemolytic anemias Iron deficiency Marrow depression Blood loss
ACT Celite	Administration of heparin for medical or surgical procedures. Administration of aprotinin.	

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
PT/INR	Administration of oral anticoagulant therapy.	
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
cTnI	Trauma Congestive heart failure. Post-operative non cardiac surgery patients. Drug toxicity, e.g. adriamycin. Coronary Vasospasm Inflammatory diseases e.g. myocarditis. Post Percutaneous Coronary Intervention (PCI). Pulmonary Embolism Sepsis Infiltrative diseases including amyloidosis, hemachromatosis, sarcoidosis, and scleroderma.	

PRINCIPLES OF MEASUREMENT

Sodium, Potassium, Chloride, Ionized Calcium, pH, and *P*CO_2

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

Lactate

is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample concentration.

***P*O_2**

is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Hematocrit

is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

ACT

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – either Celite® brand diatomaceous earth or kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT).

Glucose Test Strip

is determined amperometrically. Each strip includes an electrode containing the enzyme glucose oxidase (Precision PCx) or glucose dehydrogenase (PCx Plus). When a drop of blood is applied to the target area of the test strip, the glucose oxidase or dehydrogenase catalyzes the oxidation of glucose in the drop to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface. This generates a current that is measured by the system. The size of the current generated is proportional to the amount of glucose present in the blood drop.

PT/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has as amide linkage that mimics the thrombin–cleaved amide linkage in fibrinogen. The product of the thrombin–substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.

Troponin I/cTnI

is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

FOOTNOTES

1. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books, 1987.
2. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50 – 20, Appendix.
3. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27.

Prepared By:_____ Date: _____

Adopted: _____ Date: _____

Reviewed:_____ Date: _____

Reviewed:_____ Date: _____

Reviewed:_____ Date: _____

Revised: _____ Date: _____

i-STAT QC Log: Incoming QC

Cartridge Type:_____ Lot No.:_____ Rec'd Date: _____ Quant._____ Temp.Strip_____

Control Name: _____ Lot No.: _____ Level: _____ Exp. Date: _____ CLEW: _____

Test									
Range									
Results									
Results									

Control Name: _____ Lot No.: _____ Level: _____ Exp. Date: _____ CLEW: _____

Test									
Range									
Results									
Results									

Control Name: _____ Lot No.: _____ Level: _____ Exp. Date: _____ CLEW: _____

Test									
Range									
Results									
Results									

Lot/Shipment accepted by: _____ Date: _____

i-STAT QC Action Log

Date	Cartridge Type	Cartridge Lot No.	Date Rec'd	Quantity	Test(s) Out of Range	Corrective Action	Inspector

i-STAT QC Log: Expiration Date and Storage Conditions: Refrigerated

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Inspector

i-STAT QC Log: Expiration Date and Storage Conditions: Room Temperature

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Inspector

i-STAT Electronic Simulator Log for Analyzer Serial Number:_____ Year:_____

Date	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator

i-STAT Electronic Simulator Action Log

Date	Time	Analyzer	Failure Code or Letter	Simulator ID	Action	Pass Fail	Operator

i-STAT1 Analyzer PCx and PCx Plus Glucose Test Strip QC Log

Date	Time	Control Level	Control Lot	Strip Lot	Pass Fail	If Fail Expected Range	Result	Action	Operator